EXHIBIT 4

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VIA FEDERAL EXPRESS

Chris Gunta, R.N., Appeal Coordinator
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LEVEL II APPEAL

Re:	Claimant	: Talia Hinman
	Policyholder	: Melinda Hinman
	Policy No.	: 539153-9-DOO
	Reference Nos.	: 052563800, 052563807, 052563810 & 053364110

Dear Mr. Gunta:

As promised, this letter, all of the cited reference materials and all of the attachments constitute Ms. Hinman's Level II Appeal with respect to the referenced numbers cited above. As you will note from the material below and within the enclosures, Ms. Hinman's case compellingly documents the tragic story of the severe harm Lyme's disease caused to a young and vibrant woman with an outstanding future, and significantly, the medical necessity of her generally-accepted and successful treatment for Lyme's disease.

The plaguing problem with Ms. Hinman's remarkable journey is that despite being correctly diagnosed and treated for Lyme's disease, Assurant Health ("Assurant") nonetheless used its discretion unreasonably to deny coverage for virtually all of Ms. Hinman's treatment. Based on Assurant's denial of payment for her medically-necessary and successful treatment, Ms. Hinman is saddled with almost $95,000 in medical debt. For a young woman who has just completed high school, this mountain of debt is so significant that she will likely never recover from its impact.

Moreover, and for the reasons set forth below, under the discretionary coverage provisions at issue here, Assurant can and should cover these benefits. That is so because when Ms. Hinman's parents purchased this health insurance from Assurant, they believed that they

were purchasing coverage for conventional treatment prescribed by licensed physicians, involving medicines generally accepted for use in the practice of medicine within the United States. As a result, the highly technical contractual language upon which Assurant has relied to deny coverage is ambiguous because it does not plainly communicate to the ordinary purchaser of insurance (e.g. Talia's parents) that conventional treatment using generally-accepted medicine prescribed by a licensed physician, which was necessary to and effective in treating Ms. Hinman's illness, would be deemed experimental and medically unnecessary. It also does not conspicuously state that intravenous antibiotic treatment for Lyme disease beyond 28 days is excluded as experimental. Put similarly, but from a different point of view, given the compelling scientific evidence that treatment of late-stage Lyme disease is most effectively treated using an individualized diagnostic and treatment regimen that may in some cases warrant longer term use of intravenous antibiotic treatment, the policy language concerning "experimental" treatment could also plausibly be understood to support coverage in this case. For all of these reasons, Assurant should exercise its discretion to extend coverage to all of Ms. Hinman's medical treatment, and create a just ending to this scary and painful chapter of Ms. Hinman's life.

I. FACTUAL BACKGROUND.

A. Lyme Disease Dramatically Changed Talia Hinman.

Talia Hinman is 20 years of age, and was raised by her parents on their cherry orchard in Hood River, Oregon. For most of her life, she was well known for her vibrant personality, incredible stamina, humor, and outstanding athletic and intellectual abilities. In fact, her intellectual talents were so impressive that she was awarded the designation of a talented and gifted ("TAG") student. Her athletic achievements during her freshman and sophomore years in high school caused others to describe her as a "fireball pitcher" and "beyond her years."[1]

However, in 2003, all of this changed dramatically for Ms. Hinman. At that time, she began experiencing joint pain, progressing to an almost unbearable level by the fall of 2004. Her academic and athletic performance dropped significantly. As time went on she began having continuing head aches and other painful symptoms day and night, she lost weight from a lack of appetite, she couldn't sleep well, and subsequently missed school quite frequently.

In short, by the fall of 2004, Ms. Hinman had become a completely different person. As a result of these debilitative conditions, Ms. Hinman was forced to complete the

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[1] See Exhibit 1, Janet Cook, Lyme Labyrinth: Local women detail their desperate journeys through the maze of Lyme disease, HOOD RIVER NEWS, August 16, 2006, at B1, available at: http://www.hoodrivernews.com/KFBC%20stories/2006/065_kaleidoscope_1.htm.

remaining two years of high school from her bed at home, which cost her valuable college career-making athletic seasons and close relationships with friends. Tragically, Ms. Hinman went from being a TAG student and impressive athlete with an active social life, to living a life of solitude and barely being able to function.

B. An Expert's Successful Diagnosis and Treatment of Talia Hinman's Lyme Disease.

Between January and October of 2004, Ms. Hinman was seen multiple times by her primary care physician, Dr. Anthony Gay, and referred to numerous different specialists (e.g. a PNP Pediatric Gastroenterolgist, two additional separate Gastroenterolgists, an ENT specialist, a Neurologist, a Psychologist, an Infectious Disease specialist, and an Endocrinologist).[2] Despite all of these visits, Ms. Hinman saw no perceptible improvement in her health or overall well-being.

Seeing no improvement in her health, Ms. Hinman decided to see Dr. Christine Green, an expert in the diagnosis and treatment of Lyme disease who practices medicine in the San Francisco Bay Area. Dr. Green graduated from University of California, San Diego School of Medicine and trained in Family Practice in Stanford University's Family Practice Residency Program. She has an office in San Francisco that is devoted solely to treating Lyme disease patients. Dr. Green practices alongside Dr. Raphael B. Stricker who is a practicing clinical physician of hematolic speciality. He is also the president of the International Lyme and Associated Disease Society (ILADS). Both Dr. Green and Dr. Stricker are reputable physician experts in the diagnosis and treatment of Lyme's disease who practice in accordance with the standard of care as defined by the ILADS evidence-based guidelines for treating Lyme disease. Dr. Green has treated Lyme disease for nearly fifteen years, and all the while doing so, has carefully followed, and continues to follow, the research and scientific knowledge regarding this newly recognized bacterial disease.

In connection with her diagnosis of Ms. Hinman, Dr. Green performed a number of tests on Ms. Hinman to consider or dispel alternative etiological causes, such as thyroid dysfunction, brain abnormalities, and chemical and hormonal imbalances. As a result of these tests, along with Ms. Hinman's neurological, arthritic, and gastrointestinal symptoms, Dr. Green concluded that:

> Ms. Hinman had Lyme disease, along with Arthritis, Encephalopathy and Neuropathy, which did not resolve with oral

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[2] Exhibit 2, Ms. Hinman's medical records.

> antibiotic treatment. Ms. Hinman responded well but not completely to oral medicines. She was placed on intravenous antibiotic treatment] and is now well and able to return to work and school . . . and her previously active life.[3]

Dr. Green's diagnostic and treatment plan followed a well-established and peer-supported treatment protocol involving an individualized assessment of Ms. Hinman's needs.[4] Dr. Gay, who is Ms. Hinman's primary physician, reviewed Dr. Green's recommendations and also found them satisfactory.

II. ANALYSIS.

In its letter dated March 15, 2006, Assurant performed a Level I Appeal Review in connection with Assurant's previous adverse decision concerning certain treatment and services related to Ms. Hinman's Lyme disease. Assurant's clinical rationale for its discretionary denial decision was that "certain office visits, laboratory tests and medication administration services for presumed Lyme disease are excluded from coverage as Experimental/Investigational services."[5] Assurant relied on the following policy language to support its denial decision:

> A service or supply is Experimental or Investigational when We determine that it is:
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> 1. not of proven benefit for the particular diagnosis or treatment of a particular condition, as established by any of the reference compendia cited below or;

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[3] See Exhibit 3, Letter of Christine Green, M.D., dated January 23, 2007 ("Dr. Green's January 25 Letter") at pg. 1 (emphasis added); see also Exhibit 4, Letter of Christine Green, M.D. dated January 17, 2006.

[4] See Exhibit 5, Deborah A. Metzger, Late Stage Lyme Disease: Arguments for an Individualized Approach, (documenting the medical community's support of Dr. Green's diagnostic and treatment approach); Exhibit 6, Lorraine Johnson and Raphael B. Stricker, Treatment of Lyme Disease: A Medicolegal Assessment, EXPERT REV. ANTI-INFECT. THER. 2(4): 533-57 (2004) (same); Exhibit 7, International Lyme and Associated Diseases Society, Evidence-Based Guidelines for the Management of Lyme Disease, EXPERT REV. ANTI-INFECT. THER. 2(1 Supp): 1-13 (2004), available at: http://www.ilads.org/files/ILADS_Guidelines.pdf.

[5] See Exhibit 8, Assurant Health's Level I Appeal Review, dated March 15, 2006 ("Assurant's Denial Letter"), at pg. 3.

2. not generally recognized by the medical community as effective or appropriate for the particular diagnosis or treatment of a particular condition; or

3. provided or performed in special settings for research purposes or under a controlled environment or clinical protocol.

We will apply the following five criteria in determining whether services or supplies are Experimental or Investigational:

1. Any medical device, drug, or biological product must have received final approval to be marketed by the FDA for the particular diagnosis or condition. Any other approval; granted as an interim step in the FDA regulatory process, e.g., an Investigational Device Exemption or an Investigational New Drug Exemption, is not sufficient. Once FDA approval has been granted for a particular diagnosis or condition, use of the medical device, drug or biological product for another diagnosis or condition will require that one or more of the following established reference compendia recognize the usage as appropriate medical treatment:

    a. The American Medical Association Drug Evaluations;

    b. The American Hospital Formulary Drug Information; or

    c. The United States Pharmacopeia Drug Information.

    As an alternative to such recognition in one or more of the compendia, the usage of the drug will be recognized as appropriate if it is recommended by a clinical study and recommended by a review article in a major peer-reviewed professional journal. A medical device, drug or biological medical device, drug or biological product that meets the above tests will not be considered Experimental or Investigational.

In any event, any drug which the FDA has determined to be contraindicated for the specific treatment for which the drug has been prescribed will be considered Experimental or Investigational.

2. Conclusive evidence from the published peer-reviewed medical literature must exist that the technology has a definite positive effect on health outcomes; such evidence must include well-designed investigations that have been reproduced by non affiliated authoritative sources, with measurable results, backed up by the positive endorsements of national medical bodies or panels regarding scientific efficacy and rationale.

3. Demonstrated evidence as reflected in the published peer-reviewed medical Literature must exist that, over time, the technology leads to improvement in health outcomes, i.e., the beneficial effects outweigh any harmful effects.

4. Proof as reflected in the published peer-reviewed medical literature must exist that the technology is at least as effective in improving health outcomes as established technology, or is usable in appropriate clinical contexts in which established technology is not employable. And

5. Proof as reflected in the published peer-reviewed medical literature must exist that improvements in health outcomes, as defined in item 3 above, is possible in standard conditions of medical practice, outside clinical investigatory settings.

Assurant's discretionary decision to deny coverage rested on the conclusions of its physician-reviewer, who summarily concluded that: Ms. Hinman's medical records did not "yield information meeting the accepted definition for Lyme disease."[6] Additionally, Assurant denied coverage for intravenous antibiotic treatment for Lyme disease beyond 28 days because the same physician-reviewer claimed that such treatment was of "unproven efficacy and [therefore] is experimental/investigational."[7] Notably, this doctor did not conduct an

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[6] Id.

[7] Id.

independent exam of Ms. Hinman and carefully avoided concluding that she did not have Lyme disease or that her treatment was successful.

In reaching its first conclusion, Assurant undoubtedly had to intentionally look beyond the compelling medical evidence that supported Dr. Green's expert and correct diagnosis that Talia Hinman had late-stage Lyme disease.[8] In reaching its second conclusion, it had to act similarly in ignoring that Dr. Green's prescription of an extended course of intravenous antibiotics actually cured Ms. Hinman. Hence, the treatment protocol had a definite positive impact on Ms. Hinman's health outcome. As will be shown below, the considerable medical and scientific evidence would easily support a decision by Assurant reversing its earlier denial and extending full coverage.

A. The Definition of Experimental/Investigational Services is Ambiguous and Subject to Assurant's Broad Interpretive Discretion.

The insurance contract at issue here gives Assurant broad discretion to determine whether a service or supply is experimental or investigational, and therefore excluded from coverage. In assessing whether treatment or services are experimental or investigational, Assurant has the discretion to conclude that the service or supply meets any one of the following three characteristics:

> 1. not of proven benefit for the particular diagnosis or treatment of a particular condition, as established by any of the reference compendia cited below or; 2. not generally recognized by the medical community as effective or appropriate for the particular diagnosis or treatment of a particular condition; or 3. provided or performed in special settings for research purposes or under a controlled environment or clinical protocol.[9]

As to each of these three characteristics, Assurant has broad discretion to assess whether the treatment is of "proven benefit," or "generally recognized by the medical community as effective," or "performed in special settings for research purposes." Other than the limiting requirement concerning "special-setting" circumstances, this provision contains no meaningful limitations as to the exercise of Assurant's discretion in assessing the experimental/investigational question because terms such as "proven benefit," "generally recognized," and "effective or appropriate" are subject to broad interpretive analysis, and ultimately, as is the case here, at least two plausible interpretations based on the medical evidence.

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[8] See Exhibit 3, Dr. Green's January 25 Letter.

[9] See Exhibit 8, Assurant's Denial Letter at pg. 2.

Even with respect to the five criteria that Assurant is obligated to use in determining whether services are experimental or investigational,[10] and with the exception of the FDA-approval requirement, the Experimental/Investigation provision contains no clear limiting guidelines as to whether the existing medical evidence in this case, which supports the diagnosis and course of treatment that did in fact have a plainly positive effect on Ms. Hinman's health outcome, is sufficiently "conclusive," "demonstrated," and "at least as effective" as other treatments deemed non-experimental and/or investigational. At bottom, under this insurance contract, Assurant has virtually limitless discretion to interpret away the substantial body of compelling medical evidence that supports Dr. Green's diagnosis and treatment of Ms. Hinman as conclusive, demonstrated and at least as effective as other treatments. The problem with this kind of broad discretion is that it allows Assurant to make decisions that are influenced by cost-containment concerns, rather than objective medical and scientific standards, which appears to have happened in this case.

B. Dr. Green's Diagnosis and Treatment of Ms. Hinman's Lyme Disease Is Well Supported by Scientific Evidence and Peer-Reviewed Medical Literature, and Had a Definite Positive Effect on Ms. Hinman's Health Outcome.

In Assurant's Denial Letter, Assurant's reviewing physician correctly noted that Ms. Hinman "lived in an area where she could be exposed to infection with Lyme disease."[11] This conclusion is particularly true in Ms. Hinman's case because she lived in and traveled extensively to areas deemed "endemic" to Lyme infection.[12] Ms. Hinman lives in rural Oregon on wooded acreage surrounded by an assortment of wildlife. In late 2002, while in Oregon, she

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[10] See id. at 2-3 (listing the "five criteria" that Assurant must use in determining whether supplies or services are experimental or investigational).

[11] See id. at 3.

[12] See Exhibit 9, American Lyme Disease Foundation: U.S. Maps and Statistics, available at: http://www.aldf.com/usmap.shtml; see also Exhibit 10, Delores Raymond, Lyme Disease Misdiagnosed, Misunderstood, Mis-insured, HILLSBORO ARGUS NEWS, August 21, 2003, available at: http://www.oregonlyme.org/argus1.htm; Exhibit 11, Delores Raymond, Ashley's Long, Painful Journal – What Really Bites are the Words: 'We Don't Have Lyme in Oregon, HILLSBORO ARGUS NEWS, August 28, 2003, available at: http://www.oregonlyme.org/argus2.htm; Exhibit 12, Delores Raymond, After Years of Suffering, Ashley Finally Knows Why Lyme Disease, HILLSBORO ARGUS NEWS, September 4, 2003, available at: http://www.oregonlyme.org/argus3.htm; Exhibit 13, Trisha Yerges and Rita L. Stanley, Battling Lyme Disease: Lauren's Story, THE VALLEY NEWS, September 11, 2003, available at: http://www.oregonlyme.org/lauren12.htm.

had cared for an injured owl, which had been found to be laden with tiny ticks. From 1995 to 2003, she spent summers camping, fishing, and hunting throughout Oregon, which placed her in direct contact with appropriate deer ticks. In 2001, she traveled to France and Switzerland, which are notable areas for Lyme disease, especially western Switzerland.[13] Also, during her freshman and sophomore years in high school, she would travel with her softball team to the Canadian border/northern Washington area, to Southern California, and to Florida, all of which are endemic areas. During this time, she was regularly exposed to open, tick-infested fields. Furthermore, she often camped in Josephine County, Oregon, and played softball in Jackson County, Oregon, where a majority of the confirmed cases of Lyme disease have been found in Oregon between 2000 and 2003,[14] the number of which has increased since the 1990s.[15]

Despite this evidence of Ms. Hinman's potential exposure to Lyme disease, Assurant's physician reviewer nonetheless discounted Dr. Green's comprehensive diagnostic analysis in concluding that:

> the record includes no documentation of an erythema migrans rash and serologic tests do not meet the recommended criteria for positivity. The documented clinical symptoms might occur with a wide variety of conditions.[16]

The problem with Assurant's physician-reviewer's conclusion is that it ignores the medical and scientific evidence that there is a great potential for mis-diagnosis of Lyme disease based on inadequate reliance on the diagnostic testing referenced by Assurant's physician reviewer. For example, in cases involving patients with late-stage or latent Lyme disease, the presence of an erythema migrans rash will likely not exist because many such patients do not seek medical treatment close in time to when they were bitten by an infectious tick as these patients were not aware of ever having been bitten.[17]

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[13] See Louis Reik, Jr., LYME DISEASE AND THE NERVOUS SYSTEM (Thieme Medical Publishers 1991).

[14] See Exhibit 14, Oregon State: Acute and Communicable Disease Prevention, Lyme Disease Statistics, http://www.oregon.gov/DHS/ph/acd/diseases/lyme/cntycase.shtml (last visited July 31, 2007).

[15] See Exhibit 15, Thomas R. Burkot et al., Isolation of *Borrelia Burgdorferi* from *Neotoma Fuscipes*, *Peromyscus Maniculatus*, *Peromyscus Boylii*, and *Ixodes Pacificus* in Oregon, AM. J. TROP. MED. HYG., 60(3): 453-57 (1999).

[16] See Exhibit 8, Assurant's Denial Letter, at pg. 3.

[17] See Exhibit 16, Douglas W. Fearn, Lyme Disease and Associated Diseases: A Plain Language Introduction to Tick-Borne Diseases, LYME TIMES, available at:

As to the serologic tests referred by Assurant's physician reviewer, the U.S. Food and Drug Administration and the U.S. Center for Disease Control ("CDC") disclaimed a total reliance on only these types of tests as the primary basis for making diagnostic or treatment decisions. Rather, according to these entities, meaningful diagnosis should be based on patient history, including symptoms, exposure to the tick vector, and other physical findings,[18] which is precisely the diagnostic protocol used by Dr. Green.

Put simply, there is no uniform, definitive definition for diagnosis of Lyme disease.[19] In connection with the CDC's uniform criteria concerning Lyme disease, the CDC emphasized that its definition for Lyme disease is meant only to be used for surveillance purposes, and not for diagnostic purposes.[20] In that regard, the CDC concluded that:

> [s]urveillance case definitions establish uniform criteria for disease reporting and should not be used as the sole criteria for establishing clinical diagnoses, determining the standard of care necessary for a particular patient, setting guidelines for quality assurance or providing standards for reimbursement."[21]

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http://lymespot.blogspot.com/2005/05/basic-qas-about-lyme.html (explaining that fewer than 50 percent of all Lyme disease patients recall a tick-bite; in its nymph stage, when likely to bite, ticks are no larger than the size of a poppy seed).

[18] See Exhibit 17, United States Food and Drug Administration, Lyme Disease Test Kits: Potential for Misdiagnosis, FDA MED. BULL. (1999) (finding that even using the two-step approach, the ELISA and Western blot tests, "the sensitivity and specificity of the combined test results are inadequate;" in addition, "several factors contribute to the limitations of using ELISA, IFA, or Western blot tests for supporting patients of Lyme disease"). available at: http://www.fda.gov/medbull/summer99/Lyme.html; Exhibit 18, CDC Case Definitions for Infectious Conditions under Public Health Surveillance: Lyme Disease (*Borrelia burgdorferi*): 1996 Case definition, available at: http://www.cdc.gov/epo/dphsi/casedef/lyme_disease_current.htm. See also Exhibit 19, Nick S. Harris, An Understanding of Laboratory Testing for Lyme Disease, J. OF SPIROCHETAL AND TICK-BORNE DIS. 5: 16-26 (1998).

[19] See also Exhibit 20, David C. Owen, Is Lyme Disease Always Poly Microbial? - The Jigsaw Hypothesis, MED. HYPOTHESES 67(4): 860-64 (2006).

[20] See Exhibit 18.

[21] See Exhibit 21, CDC: Lyme Disease Statistics, http://www.cdc.gov/ncidod/dvbid/lyme/ld_statistics.htm (emphasis added) (last visited July 31, 2007).

Courts have also acknowledged that there is no definable test in completely confirming or denying an active Lyme-disease infection. See, e.g., Foxbilt Elec. v. Stanton, 583 So. 2d 720, 722 (Fla. 1st Dist. App. 1991); Cigna Ins. Co. of Tex. v. Evans, 847 S.W.2d 417, 419 (Tex. App. Dist. 1993)("[t]here is evidence that Lyme disease has a lengthy incubation period and that it is not easily diagnosed"); Risenhoover v. Bayer Corp. Group Health Plan, 83 F.Supp.2d 408 (S.D.N.Y. 2000) ("[i]t is also clear that Lyme disease may be difficult to diagnose, and particularly so in this case, where over the years plaintiff's condition" was diagnosed with a number of different problems); Schwob v. Standard Ins. Co, 2006 WL 752855 n.3 (W.D. Okla. 2006) (unpublished) ("[t]here is no test currently commercially available that can positively diagnose Lyme disease, and there is no test that indicates active infection compared with prior exposure in a patient who has been treated and cured").

The lack of a consensus concerning the diagnosis of Lyme disease highlights the unreasonableness of Assurant's decision to reject Dr. Green's diagnostic protocol and the substantial body of medical and scientific support behind it.[22] Based upon the emerging and substantial body of medical evidence supporting Dr. Green's approach, Assurant could accept coverage in this case by simply opening its discretionary "eyes" to this evidence, which it most certainly can do under the contract's discretionary terms. In doing so, Assurant could easily conclude that Dr. Green's diagnosis of Ms. Hinman as having Lyme disease was sufficiently "conclusive," "demonstrated," "medically-accepted" and "at least as effective" as other diagnostic criteria.

As to Dr. Green's treatment prescription of long-term intravenous antibiotics, as noted above, Assurant's physician-reviewer concluded that, aside from the alleged failure of Dr. Green's diagnosis to meet "established diagnostic criteria" (which had the effect of exlcuding from coverage virtually all of Ms. Hinman's treatment), Dr. Green's prescription of intravenous antibiotic treatment beyond 28 days was "of unproven efficacy and is [therefore] experimental/investigational."[23]

The problem with this conclusion is similar to the problem concerning the diagnosis, namely that it ignores the substantial body of medical evidence in support of the use of long-term intravenous antibiotic treatment for patients with chronic Lyme disease. This emerging body of medical evidence proves that a large and growing segment of the medical community views longer-term intravenous antibiotic treatment as beneficial to improving the health outcomes of patients with chronic Lyme disease infections.[24]

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[22] See Exhibits 3-7.

[23] See Exhibit 8, Assurant's Denial Letter, at pg. 3.

[24] See Exhibits 3-7, 17-21.

The lack of an overwhelming consensus concerning the diagnosis and treatment of Lyme disease highlights the problem with Assurant clinging to the "traditional" school of thought regarding this dangerous disease, which basically opines that Lyme disease should be treated with antibiotics for a term of no greater than thirty days because any antibiotics thereafter would not be effective nor safe.[25] In this case, Assurant misused its discretion by favoring this traditional view and substantially discounting the emerging medical evidence, Dr. Green's expertise, and the medical necessity of Talia's treatment. In fact, Assurant's discretionary practice of ignoring the emerging medical evidence reflects "an entrenched and growing ignorance and neglect of the severity of Lyme disease, while its victims continue to suffer."[26]

In that regard, the National Academy of Science's Institute of Medicine ("IOM") has reported that for a new best practice to be considered "medically necessary," it can take up to seventeen years to reach the average doctor.[27] Hence, the point at which a procedure shifts from being new and experimental to usual and customary is unclear as a practical matter, which further underscores the ambiguity inherent within the Experimental/Investigational provisions – "conclusive," "demonstrated," "medically-accepted," and "at least as effective" – upon which Assurant relies.

Dr. Green, who is an expert in the diagnosis and treatment of Lyme disease, followed the emerging and medically-documented practice in treating Ms. Hinman. The efficacy of this medical practice and other supportive evidence concerning the treatment of patients with chronic Lyme disease caused Columbia University's Lyme Disease Research Center, the first center to focus on chronic Lyme disease, to conclude that at "this point in medical history, decisions about the treatment of the patient with chronic Lyme disease need to be individually shaped by the clinician's experience, the patient's clinical profile and history of antibiotic

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[25] But see Exhibit 22, Daniel J. Cameron, Generalizability in Two Clinical Trials of Lyme Disease, EPIDEMIOLOGICAL PERSPECTIVES & INNOVATIONS, 3:12-19 (2006) (concluding that applying findings to target populations with characteristics that differ from those included in Klempner's trials is inappropriate and may limit options for chronic Lyme disease patients who might benefit from extended antibiotic treatments), available at: http://www.epi-perspectives.com/content/3/1/12.

[26] See Exhibit 23, Raphael B. Stricker et al., Lyme Disease: The Quest for Magic Bullets, CHEMOTHERAPY 52(2), 54 (2006).

[27] See Exhibit 24, E. Andrew Balas, Information Systems Can Prevent Errors and Improve Quality, J. OF THE AM. MED. INFORMATICS ASS'N 8(4): 398-99 (2001); see also Institute of Medicine, HEALTH PROFESSIONS EDUCATION : A BRIDGE OF QUALITY (A.C. Greiner and E. Knebel, eds., D.C. National Academy Press 2003).

responsiveness, and the emerging medical literature."[28] The United States Supreme Court confirmed the basic correctness of this approach in explaining that "eligibility decisions cannot be untangled from physicians' judgment about reasonable medical treatment." Pegram v. Herdrich, 530 U.S. 211, 229 (2000).

This medical evidence also confirms that the medical community accepts the use of long-term antibiotic treatment for treating latent Lyme disease. In that regard, a number of published studies involving non-randomized surveys of physicians in endemic areas found more than half of them prescribing extended courses of antibiotics for chronic Lyme disease.[29] This emerging school of medical opinion also believes that traditional Lyme-disease treatment is effective only if administered shortly after the tick bite occurs. However, as noted above, most patients do not realize they have been bitten or that they may have Lyme disease until several weeks or months after the bite occurs.[30] As a result, physicians may initially mis-diagnose some patients as having Chronic Fatigue Syndrome even though the patients may actually have chronic Lyme disease.[31] When the disease is left untreated for such time, it can result in a late-stage form of Lyme disease that requires prolonged antibiotic treatment, lasting much longer than the approximately thirty-day treatment course recommended by the traditional view.[32] The

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[28] See Exhibit 25, Columbia University's Lyme Disease Research Center, available at: http://www.columbia-lyme.org/flatp/treatment.html.

[29] See Exhibit 26, M.H. Ziska et al., Physician Preferences in the Diagnosis and Treatment of Lyme Disease in the United States, INFECTION 24(2): 182-86 (1996) (nearly 57 percent of responding physicians treated persistent Lyme disease for three months or more); Exhibit 27, S.C. Eppes et al., Physician Beliefs, Attitudes, and Approaches Toward Lyme Disease in an Endemic Area, CLIN. PEDIATR. (PHILA) 33(3): 130-34 (1994); See also Exhibit 23.

[30] See Exhibit 28, A.R. Pachner, Neurologic Manifestations of Lyme Disease, The New 'Great Imitator,' REV. INFECT. DIS. 11 (Supp. 6): 1482-86 (1989) ("a lengthy latency ... appears to exist in Lyme disease, with neurological symptoms not becoming manifest for months or even years").

[31] See Exhibit 29, Samuel Shor, Lyme Disease Presenting as Chronic Fatigue Syndrome, J. OF CHRONIC FATIGUE SYNDROME 13(4): 67-75 (2006).

[32] See Exhibit 30, Raphael B. Stricker, Counterpoint: Long-Term Antibiotic Therapy Improves Persistent Symptoms Associated with Lyme Disease, CLIN. INFECT. DIS. 45(1): 149-57 (2007); Exhibit 31, Sam T. Donta, Macrolide Therapy of Chronic Lyme Disease, MED. SCI. MONIT. 9(11): 136-42 (2003), available at: http://www.medscimonit.com/pub/vol_9/no_11/3706.pdf; Exhibit 32, J. Oksi et al., Comparison

International Lyme and Associated Diseases Society (ILADS) recognizes this emerging school of thought,[33] and the CDC concedes that long-term treatment can benefit some patients suffering from with latent Lyme disease.[34]

Based on Ms. Hinman's medical history, Dr. Green decided that antibiotics should be given for more than thirty days. This treatment is supported by medical evidence and proved to be successful. Assurant should not deny coverage for peer-supported, necessary and effective treatment simply because it does not fit with the "traditional" view of treatment for Lyme disease. Ultimately, this is unfair and unsafe to patients, and dangerously tips coverage decisions away from health outcomes and in favor of cost-containment considerations.

This public-health concern has caused a few states to react with laws that protect public health in this area. For example, Rhode Island and Connecticut recognized the benefits of long-term treatment for chronic Lyme disease and a diagnostic approach that is individually shaped by the clinician's experience, the patient's clinical profile and history of antibiotic responsiveness, and the emerging medical literature by passing legislation that prevents insurance companies from denying coverage for long-term antibiotic treatments. See R.I. Gen. Laws § 27-18-62 (2003) ("Every individual or group hospital or medical expense insurance policy ... shall provide coverage for diagnostic testing and long-term antibiotic treatment of chronic Lyme disease when determined to be medically necessary and ordered by a physician ... after making a thorough evaluation of the patient's symptoms, diagnostic test results and response to treatment. Treatment otherwise eligible for benefits pursuant to this section shall not be denied solely because such treatment may be characterized as unproven, experimental, or investigational in nature."). Accord Conn. Gen. Stat. § 38a-492h (1999) ("Each individual health insurance policy ... shall provide coverage for Lyme disease treatment including not less than thirty days of

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of oral cefixime and intravenous ceftriaxone followed by oral amoxicillin in disseminated Lyme borreliosis, EUR. J. CLIN. MICROBIOL. INFECT. DIS. 17(10): 715-19 (1998); Exhibit 33, Alan B. MacDonald et al., Clinical Implications of Delayed Growth of the Lyme Borreliosis Spirochete, Borrelia Burgdorferi, ACTA TROP. 48(2): 89-94 (1990).

[33] See Exhibit 7. See also Exhibit 34, Phillips S. Bransfield et al., Evaluation of Antibiotic Treatment in Patients with Persistent Symptoms of Lyme Disease: An ILADS Position Paper (2003), available at: http://www.ilads.org/position2.html.

[34] See Exhibit 35, CDC: Lyme Disease Treatment and Prognosis, http://www.cdc.gov/ncidod/dvbid/lyme/ld_humandisease_treatment.htm ("[a] few patients, particularly those diagnosed with later stages of disease, may have persistent or recurrent symptoms. These patients may benefit from a second 4-week course of therapy.") (emphasis added) (last visited July 31, 2007).

intravenous antibiotic therapy, sixty days of oral antibiotic behavior, or both, and shall provide further treatment if recommended by a board certified rheumatologist, infectious disease specialist or neurologist"). This legislation reflects the reality that certain health-insurance carriers cling to the old-school view and refuse to give the emerging medical evidence its proper weight, which would mean providing coverage to suffers of chronic Lyme disease. Assurant can and should do better.

III. CONCLUSION.

Assurant should use its discretionary power to reverse its denial decision and extend coverage to Ms. Hinman's successful treatment for Lyme disease. As explained above, there is ample evidence supporting Dr. Green's diagnostic and treatment protocol as medically-approved, conclusive, demonstrated and if not more effective, at least as effective as the other, short-term approach. Hence, Assurant is wrong in denying coverage on the rationale that Ms. Hinman received "experimental" care.

Moreover, the Experimental/Investigational provision is ambiguous. In such a case, the law is very clear: the ambiguity must be resolved in favor of coverage. Here, given the substantial body of medical evidence in support of Ms. Hinman's treatment, its success, and Dr. Green's expert treatment approach, a court will resolve that ambiguity in Ms. Hinman's favor. Rather than forcing a judicial decision, Assurant should do the right thing at this stage, extend coverage, and end Ms. Hinman's difficult journey on a just note.

Also, in connection with this Level II Appeal, we respectfully request the opportunity to appear before the Appeal Panel at a hearing. Please let me know the time, date and place of this appearance as well as the names, occupations and titles of the individuals serving on the Appeal Panel. Your anticipated thoughtful consideration of this appeal is appreciated.

Very truly yours,

Christopher Lundberg

CGL:lsh
Enclosures
cc: Melinda Hinman